NOV - 3 2000

K001788

510(k) Summary

1. **Name/Address of Submitter:** eRecords Enterprises
   801 York Mills Road – Suite 314
   Toronto, Ontario M3B 1X7
   Canada

2. **Contact Person:** Edward A. Goss
   Project Manager
   (416) 383-0046

3. **Date Summary Prepared:** May 26, 2000

4. **Device Name:** eStation Model DR200 Electronic Stethoscope

5. **Predicate Devices:** Meditron Electronic Stethoscope,
   CareTone II Telephonic Stethoscope

6. **Device Description and Intended Use:**

   The eStation Electronic Stethoscope is intended for use as a diagnostic aid in patient diagnosis, treatment and monitoring. It amplifies, records, stores, plays back, and transmits sounds associated with the heart and other internal organs. Significant components include a control unit, installation software; power supply; adaptor, earphones, chest piece assembly, and communication cable. The user must supply a personal computer with a Microsoft Windows 95/98 or NT 4.0 operating system and CD-ROM drive. The stored sounds can be transmitted via e-mail.

7. **Brief Description of Nonclinical Testing:**

   The specifications for the environmental and electromagnetic compatibility (EMC) testing of the eStation reference appropriate voluntary standards. All product specifications were met.

8. **Brief Description of Clinical Testing:**

   Clinical study information was not submitted for the purpose of demonstrating substantial equivalence to legally marketed electronic stethoscopes.

9. **Conclusions Drawn:**

   The indications for use are consistent with those for legally marketed electronic stethoscopes. Differences in technological characteristics from those of the cited predicate devices do not raise new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 3 2000

Mr. Edward Goss
Project Manager
eRecords Enterprises
801 York Mills Road, Suite 314
Toronto, Ontario, M3B 1X7, Canada

Re: K001788
eStation Electronic Stethoscope, Model DR200
Regulatory Class: II (two)
Product Code: 74 DQD
Dated: September 20, 2000
Received: September 21, 2000

Dear Ms. Goss:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the

Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4346. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices
and Radiological Health

Enclosure

K001788

Indication for Use

510(k) Number (if known): _____

Device Name: eStation Model DR200 Electronic Stethoscope

Indication for Use:

The eStation is an electronically amplified device intended for use in projecting the sounds associated with the heart and other internal organs. The eStation records, stores, plays back, and electronically transmits these sounds.

Concurrence of CDRH Office of Device Evaluation

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K001788

Prescription Use ____ **OR** **Over-the-counter Use** ____
(per 21 CFR 801.109)